REMARKS

Reconsideration of the above-identified application in view of the aforementioned amendments and following arguments is respectfully requested.

Claims 1-2, 9, 15, 25, 27, 32, 39 and 47-49 have been amended. No new matter has been added as a result of these amendments. Claims 73-80 have been added and no new matter has been added as a result of the addition of these claims.

Claims 6-8, 18-20, 36-38 and 51-58 have been canceled in response to a restriction requirement. Applicants reserve the right to prosecute these claims in one or more divisional applications. Claims 69-72 have been deleted and replaced with claims 73-80. New claims 73-80 better define the claimed invention.

Claims 25 and 32 have been amended to correct typographical errors. Claims 1-2, 9, 15, 27, 39 and 47-49 have been amended to better describe the claimed invention.

Claims 9-17, 21-26, 39-50 and 59-68 remain rejected under 35 U.S.C. Section 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention. Specifically, the Office Action states that Applicants have not adequately described the "broad genus encompassing the multitude of claimed species". The Office Action states that "Applicants have only demonstrated the presence of a TCB gene cluster in a single population of plants derived from crossing inbred W22 with a particular teosinte accession from a particular geographic location. Applicants have not described any other TCG gene cluster or *Tcb* locus obtained from different populations of teosinte, or even from different crosses of teosinte and maize." (Office Action, pages 3-4). Finally, the Office Action concludes that "Applicants have not disclosed structural characteristics which are conserved throughout their genus that are correlated with function." Applicants respectfully traverse this rejection.

The inquiry into whether the description requirement is met is determined on a case-by-case basis and is a question of fact. Section 2163 *Manual of Patent Examining Procedure* (8th Edition, Rev. 1, Feb. 2003). When a question regarding the adequacy of the written description arises, the fundamental factual inquiry is whether the specification conveys to those skilled in the art, as of the filing date sought, that Applicant was in possession of the invention being claimed. Section 2163.02 *Manual of Patent Examining Procedure* (8th Edition, Rev. 1, Feb. 2003). Possession can be shown in a number of ways. For example, an Applicant can show possession by: (1) an actual reduction to practice of the claimed invention; (2) a clear depiction of the invention in detailed drawings or in structural chemical formulas which permit a person skilled in the art to clearly recognize that applicant had possession of the claimed invention; or (3) any description of sufficient, relevant, identifying characteristics so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention. *Id.*

A description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the Examiner to rebut the presumption. Section 2163.04 *Manual of Patent Examining Procedure* (8th Edition, Rev. 1, Feb. 2003). The Examiner, therefore, must have a reasonable basis to challenge the adequacy of the written description. *Id.* The Examiner has the initial burden of presenting by a preponderance of the evidence why a person skilled in the art would not recognize in an applicants disclosure a description of the invention as defined by the claims. *Id.* "A general allegation of unpredictability in the art is not a sufficient reason to support a rejection for lack of adequate written description." *Id.* The *Manual of Patent Examining Procedure* even cautions Examiners that "rejection of an original claim for lack of written description should be rare." (See Section 2163 *Manual of Patent Examining Procedure* (8th Edition, Rev. 1, Feb. 2003)).

Contrary to the arguments made in the Office Action, Applicants submit that the specification adequately describes the claimed invention. Specifically, in describing the TCB trait of the present invention, Applicants have provided information of the location of the gene cluster responsible for this trait (the short arm of chromosome 4 between map units

40-85 as shown in Figure 1) and that this gene cluster is expressed dominantly (See page 15 of the specification). Applicants have also described the location of the *Tcb* locus (See page 15 of the specification, lines 16-20). Applicants have also described the approximate location of the modifier gene (See page 16 of the specification, lines 23-26). Applicants have also provided the molecular markers that can be used to identify the gene cluster associated with the TCB trait (See page 18 of the specification, lines 14-30). The use of these markers in conjunction with deposited dent inbred W22-TCB allows those of ordinary skill in the art to use routine, well-known techniques to identify other maize plants that contain the TCB trait.

In view of this detailed description provided in the specification, Applicants respectfully submit that the Office Action fails to provide sufficient factual evidence to rebut the presumption that the description as filed is inadequate. Moreover, the Office Action fails to present any factual evidence as to why a person of ordinary skilled in the art would not recognize in Applicants disclosure a description of the invention as defined by the claims. Therefore, in view of the absence of such evidence, Applicants submit that this rejection should be withdrawn.

Claims 9-17, 21-26, 39-50 and 59-68 remain rejected under 35 U.S.C. Section 112, first paragraph, as being enabled for claims limited to maize plants containing the TCB trait from maize line W22-TCB (ATCC No. PTA-1601) and methods of using these plants. The Office Action states that the specification does not reasonably provide enablement for claims broadly drawn to any maize plant containing any TCB trait or gene cluster, any Tcb locus, any "modifier gene", any "pollen effect" gene, any "silk effect" gene, or methods of using them. The Office Action goes on to state "[T]he Examiner maintains that the cited art indeed demonstrates the unpredictability inherent in the process of identifying and characterizing genes involved in cross-incompatibility in maize. In the absence of any characterization or identification of other sources of TCB gene clusters, Tcb loci, pollen or silk effect or modifier genes; Applicants' assertions that the prior art merely taught mistakes which were later corrected are not persuasive or probative. Regarding Goldman et al., the reference clearly teaches that molecular marker-mediated gene identification and

characterization is quite dependent upon the choice of parents utilized as the source of the cross. Thus the assignment of the TCB gene cluster on chromosome 4 at a particular location with respect to other molecular markers, based upon the crossing of W22 and a particular teosinte parent, does not provide sufficient assurance that any TCB gene cluster would be found on the same chromosome at the same location if it were derived from different parents. Applicants' failure to actually characterize the number of loci present in the TCB gene cluster or their identity, and the vague characterization of genes conferring pollen or silk effects or modifications as stated above; further add to the unpredictability inherent in identifying other TCB gene clusters or their components from other non-exemplified sources, characterizing these gene cluster components, and incorporating them into other maize plants." (Office Action, pages 5-6). Applicants respectfully traverse this rejection.

The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent application coupled with information known in the art without undue experimentation (*Manuel of Patent Examining Procedure*, 8th Edition, August 2001). As discussed in their previous Amendment, Applicants have described in their specification how the TCB trait comprises a TCB gene cluster that is expressed dominantly and located on the short arm of chromosome 4, between map units 40-85 (See Figure 1). The TCB gene cluster further includes a *Tcb* locus. Moreover, as described in the specification on page 18, lines 14-20, a number of molecular markers, including those between phi021 and nc005 shown in Fig. 1 and the markers including and between umc 1117 and bnlg 490 shown in Fig. 3B can be used to identify the *Tcb* locus. Additionally, as further described in the specification on page 15, lines 19-20, the *Tcb* locus is located at about 6 map units (or centiMorgans) distal to the *sugary1* marker on chromosome 4S, about 40 map units (or centiMorgans) from the *Ga1* marker. The *Tcb* locus contains genes responsible for the silk effect function and pollen effect function. The characteristics of the gene(s) that encode the "silk effect" and "pollen effect" are described in detail on page 15, lines 21 – page 16, lines 9-15.

With respect to the "modifier genes", the specification on page 16, lines 23-30 and

page 17, line 1, describes the modifier genes and how such genes can be located. In fact, the specification on page 16, lines 25-26 describes at least one modifier gene that modifies the effect of the *Tcb* locus and is located near the *Tcb* locus in the direction of the *Ga1* marker (see Fig. 1).

Applicants submit that plants grown from the seeds of inbred line W22-TCB along with the description on pages 15 and 16 of the specification, as well as the molecular markers described on page 18 of the specification can all be used in combination by those skilled in the art to identify other plants that exhibit TCB traits, *Tcb* gene clusters, *Tcb* loci and modifier genes using routine experimentation in the art.

The Examiner simply has not provided any evidence other than his opinion that one reasonably skilled in the art could not make or use the presently claimed invention based upon the specification as filed without undue experimentation. Thereupon, in view of the aforementioned arguments, Applicants submit that this rejection should be withdrawn.

Claims 1-5, 9-17, 21-35, 39-50, 55-66 and 69-72 are rejected under 35 U.S.C. Section 102(b) as being anticipated by Kermicle et al. (1990). Applicants respectfully traverse this rejection.

Page 7 of the Office Action states, "[T]hus, the maize plants taught by Kermicle et al appear to be the same as those claimed, even though the claimed maize plants have different names for their various loci. Thus any method of using the claimed maize plants were also taught by Kermicle et al, who teach the same methods being applied to their plants. See *In re Best*, 195 USPQ 430, 433 (CCPA 1977), which teaches that where the prior art product seems to be identical to the claimed product, except that the prior art is silent as to a particularly claimed characteristic or property, then the burden shifts to Applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention."

Applicants respectfully submit that the maize plants taught by Kermicle et al. (1990) <u>are not</u> the same as the maize plants of the present invention. In order to assist the Office's understanding of how the claimed invention differs from the plants taught by Kermicle et al.

(1990), a summary of the differences are provided below in Table A.

TABLE A

	Maize plants that contain a gene cluster that encodes the teosinte crossing barrier (TCB) trait (Plants of the Present Invention)	Maize plants that contain genes that encode the TIC trait described by Kermicle et al. (1990).
Is the TIC-CP1 phenotype a component of the cross-incompatibility barrier?	NO - NOT A COMPONENT OF THE TCB TRAIT	YES - A COMPONENT OF THE TIC TRAIT
Is the TIC-CP2 phenotype a component of the cross-incompatibility barrier?	YES - A COMPONENT OF THE TCB TRAIT	YES - A COMPONENT OF THE TIC TRAIT
Is at least one modifier gene identified and described?	YES	NONE DESCRIBED
Is a gene that encodes for the silk effect function identified and described?	YES	NONE IDENTIFIED, DESCRIBED OR SUGGESTED
Are any linked molecular markers described?	YES	NONE IDENTIFIED, DESCRIBED OR SUGGESTED

Additionally, also enclosed is a 37 C.F.R. Section 1.132 Declaration of Dr. Jerry L. Kermicle (hereinafter referred to as the "Kermicle Declaration"). As discussed in Paragraph 5 of the Kermicle Declaration, Kermicle et al. teach that the two (2) components of the TIC trait are (1) TIC-CP1; and (2) TIC-CP2. Additionally, Kermicle et al. hypothesized that the TIC trait encompassed another factor or factors which were unknown to the authors in 1990.

As the Kermicle Declaration discusses in Paragraph 6, after several years of further experimentation and breeding with plants containing the TIC trait, additional maize plants were developed that exhibited a cross-incompatible phenotype. These plants exhibited a phenotype different from the phenotype exhibited by the maize plants containing the TIC trait. This phenotype was referred to as the "teosinte crossing barrier" or TCB trait. Unlike plants containing the TIC trait that exhibited the TIC phenotype, plants exhibiting the TCB trait and the TCB phenotype do not contain TIC-CP1. As explained in the Kermicle Declaration, this

finding was surprising in view of the work described in Kermicle et al. where TIC-CP1 was considered to be one of the two components of the cross-incompatibility barrier comprising the TIC trait (See Paragraph 7 of the Kermicle Declaration). In fact, Applicants submit that one of ordinary skill in the art reading Kermicle et al. (1990) would reasonable concluded that TIC-CP1 would be a necessary component of the TCB trait.

As shown in the above Table A as well as Paragraph 8 of the Kermicle Declaration, in addition to discovering that TIC-CP1 was not a component of the TCB trait, the inventors further discovered that the TCB trait was encoded by a gene cluster comprising a *Tcb* locus and at least one modifier gene. The *Tcb* locus governs recognition between pollen and pistil. Kermicle et al. did not teach any modifier gene. Additionally, Kermicle et al. did not identify, teach the silk effect function of the TCB trait nor did it identify, disclose or suggest any molecular markers that might be useful for identifying the TIC trait. The present application identifies and describes several molecular markers that allow one of ordinary skill in the art to identify plant material containing the gene cluster that encodes for the TCB trait using routine techniques known in the art. Therefore, as evidenced by the above-information, the plants of Kermicle et al. and the plants of the claimed present invention are not identical.

Thereupon, based upon the arguments provided above, Kermicle et al. fail to disclose or each and every element of the claimed invention. Therefore, Applicants submit that this rejection should be withdrawn.

Claims 1-5, 9-17, 21-35, 39-50, 55-66 and 69-72 are rejected under 35 U.S.C. Section 103 as being obvious over Kermicle et al. (1990) taken with Nelson. Applicants respectfully traverse this rejection.

Kermicle et al. (1990) was discussed above. Nelson is a chapter from *The Maize Handbook*. In this chapter, Nelson reviews various gametophyte factors in maize. The first Office Action referred to various paragraphs in Nelson. Specifically, the paragraph bridging pages 496-497, the bottom two paragraphs on page 499, the top paragraph on page 500, and the second full paragraph on page 501.

The paragraph bridging pages 496-497 discusses the crosses (specifically those involving crosses between Rice Popcorn and sweet corn (*sugary1*)) that lead to the identification of the fourth chromosome locus, *gametophyte factor1 (ga1)*. *Gametophyte factor1* is different from the TCB trait. The recessive allele, ga1, at the gametophyte *factor1* locus is typically found in dent corn. Specifically, *ga1* pollen is capable of fertilizing other dent corn that contains this locus. However, *Ga1-s/Ga1-s* popcorn is not fertilized by *ga1* pollen. However, *Ga1 ga1* heterozygotes are usually fertilized by *ga1 ga1* homozygotes.

The second to last paragraph on page 499 of Nelson discusses how the inability of *Ga1-s/Ga1-s* plants to set seed with *ga* pollen can be exploited to protect maize being grown for special uses from contamination by dent (*ga*) pollen during hybrid seed production and the production of the crop itself. The last paragraph on page 499 that is carried over on to page 500 discusses the work described by Nelson in *Genetics* 37:101-124 (1952). This paragraph discusses the experiments conducted by Nelson relating to cross-sterility among popcorns using a series of reciprocal crosses. Nelson employed 10 popcorn inbreds from a number of varieties and a dent inbred, *Hy*, that was known not to be able to effect fertilization on several popcorn inbreds. What is not reported here is that in this work Nelson found that the success of the cross depended on whether or not *Ga1-s* was present as homozygote or a heterozygote. Specifically, Nelson found that when *Ga1-s* was present as a homozygote, the cross failed; but if present as a heterozygote, that the success of the cross was variable (See Evans et al., *Theor. Appl. Genet.*, 103:259-265, 259 (2001)).

In the second full paragraph on page 501 Nelson discusses the work of Kermicle et al. (1990) reported in *Maydica*, 35:399-408 (1990). The work of Kermicle et al. (1990) has been discussed previously. In fact, Applicants submit that with respect to its teachings regarding the TIC phenotype, Nelson does not teach anything new that has not already been taught by Kermicle et al. (1990).

Neither Kermicle et al. (1990) nor Nelson disclose or suggest the plants of the claimed invention. As discussed previously, the plants described by Kermicle et al. are not identical to

the plants of the claimed invention. There is nothing in Kermicle et al. (1990) or in Nelson, individually or collectively, that discloses or suggests plants having the phenotype of the plants of the present invention. In fact, Applicants submit that one of ordinary skill in the art reading Kermicle et al. (1990) would expect TIC-CP1 to be a component of the TCB trait that encodes the TCB phenotype. Moreover, there is absolutely nothing in Kermicle et al. that discloses or suggests at least one modifier gene, a gene that encodes for the silk effect function or any disclosure of molecular markers that allow one of ordinary skill in the art to identify plant material containing the gene cluster and at least one modifier gene that encode for the TCB trait using routine techniques known in the art. Therefore, Applicants submit that this rejection should be withdrawn.

Applicants submit that the claims are now in condition for allowance.

If any additional fees are incurred as a result of the filing of this paper, authorization is given to charge deposit account number 23-0785.

Respectfully submitted,

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